

## REMARKS

### *1. Status of claims*

After entry of the above amendment, claims 1-8, 10-17, 19-28, 30-33, 35, and 37 are pending and under consideration.

### *2. Support for amendment*

The above amendment finds support in the specification and drawings at p. 1, lines 13-16; p. 4, lines 25-27; and Figure 1. No new matter has been added by this amendment.

### *3. Claim rejections under 35 U.S.C. § 102*

First, the Examiner rejected claims 1-4, 6, 10-11, 13-14, 16, 19-20, 22-25, and 30-33 under 35 U.S.C. § 102(e) as being anticipated by Michelson, US 6,537,320 ("Michelson"). After entry of the above amendment, Applicants traverse this rejection.

Michelson discloses a spinal fusion implant which comprises bone penetrating protrusions configured to penetrate the endplates of vertebrae and inserting the implant into a space defined by adjacent vertebrae and in part by an intervertebral disc annulus (Abstract and Figs. 3A-B). The skilled artisan will understand that configuring the bone penetrating protrusions of Michelson will involve imparting physical and structural properties to the protrusions to render them effective for penetrating vertebral endplates.

In contrast, the present claims recite an apparatus for repairing an intervertebral disc defect, which has a periphery surrounded by annular tissue, wherein the apparatus comprises at least one annulus engaging member configured to engage annular tissue, or methods for repairing an intervertebral disc defect by use of the apparatus. The skilled artisan will

understand that configuring the annulus engaging member(s) will involve imparting physical and structural properties to the members to render it effective for engaging annular tissue. The physical and structural properties required to effectively engage annular tissue (primarily comprising fibrocartilage) would differ from those required to penetrate vertebral endplates (primarily comprising cortical bone without or with a layer of hyaline cartilage). (Such configuring is a matter of routine experimentation for the skilled artisan having the benefit of the specification).

Michelson does not teach at least these elements of the present claims, and therefore cannot anticipate them. Applicants request this rejection of claims 1-4, 6, 10-11, 13-14, 16, 19-20, 22-25, and 30-33 be withdrawn.

Second, the Examiner rejected claims 1-2, 6, 10-11, and 16 under 35 U.S.C. §102(e) as being anticipated by Boyer, II, *et al.*, US 6,767,369 (“Boyer”). After entry of the above amendment, Applicants traverse this rejection.

Boyer discloses a plug for filling a vacancy in bone tissue (col. 3, lines 66-67; col. 4, lines 37-56), wherein the plug may be configured to be threadably received in a vacancy in bone tissue (col. 12, lines 42-45; Figure 3N). The skilled artisan will understand that configuring the thread of Boyer will involve imparting physical and structural properties to the thread to render it effective for engaging bone tissue.

As stated above, the present claims recite an apparatus for repairing an intervertebral disc defect, which has a periphery surrounded by annular tissue, wherein the apparatus comprises at least one annulus engaging member configured to engage annular tissue, or methods for repairing an intervertebral disc defect by use of the apparatus. The skilled artisan will understand that configuring the annulus engaging member(s) will involve imparting physical and

structural properties to the members to render it effective for engaging annular tissue. The physical and structural properties required to effectively engage annular tissue would differ from those required to engage bone tissue.

Boyer does not teach at least these elements of the present claims, and therefore cannot anticipate them. Applicants request this rejection of claims 1-2, 6, 10-11, and 16 be withdrawn.

#### Claim rejections under 35 U.S.C. § 103

First, the Examiner rejected claims 5, 7-8, 12, 15, 17, 21, 26-28, 35, and 37 under 35 U.S.C. §103(a) as being unpatentable over Michelson, as applied above, in view of Boyce *et al.*, US 6,294,187 (“Boyce”). In light of the above amendment, Applicants traverse this rejection.

As discussed above, Michelson discloses a spinal fusion implant. Boyce discloses a load-bearing osteoimplant and a method for repairing bone using the same (Abstract). The combination of Michelson and Boyce neither teaches nor suggests the present claims, which recite an apparatus for repairing an intervertebral disc defect, which has a periphery surrounded by annular tissue, wherein the apparatus comprises, *inter alia*, at least one annulus engaging member configured to engage annular tissue, or methods for repairing an intervertebral disc defect by use of the apparatus. Therefore, Applicants request this rejection of claims 5, 7-8, 12, 15, 17, 21, 26-28, 35, and 37 be withdrawn.

Second, the Examiner rejected claims 3 and 13 under 35 U.S.C. §103(a) as being unpatentable over Boyer in view of Michelson, as applied above. In light of the above amendment, Applicants traverse this rejection.

As discussed above, Boyer discloses a plug for filling a vacancy in bone tissue and Michelson discloses a spinal fusion implant which comprises bone penetrating protrusions

configured to penetrate the endplates of vertebrae. The combination of Boyer and Michelson neither teaches nor suggests the present claims, which recite an apparatus for repairing an intervertebral disc defect, which has a periphery surrounded by annular tissue, wherein the apparatus comprises, *inter alia*, at least one annulus engaging member configured to engage annular tissue, or methods for repairing an intervertebral disc defect by use of the apparatus. Therefore, Applicants request this rejection of claims 5, 7-8, 12, 15, 17, 21, 26-28, 35, and 37 be withdrawn.

Third, the Examiner rejected claims 19-23, 25-28, 30-33, and 37 under 35 U.S.C. §103(a) as being unpatentable over Bao *et al.*, US 6,224,630 (“Bao”) in view of Michelson, as applied above. In light of the above amendment, Applicants traverse this rejection.

Bao discloses a device for insertion into a defect in the annulus of an intervertebral disc (Abstract). The device is preferred to comprise a non-biodegradable polymer, polyvinyl alcohol (PVA) (col. 5, lines 30-61). The device can comprise an expanded or enlarged end portion to prevent migration (col. 7, lines 61-67). As discussed above, Michelson discloses a spinal fusion implant.

The skilled artisan would have no motivation to combine the teachings of Michelson and Bao, as the two references are directed toward diametrically opposite therapies and therapeutic outcomes (i.e., spinal fusion v. non-fusion). Even if, *arguendo*, such motivation existed, the combination would not guide the skilled artisan to use a plug having an annulus engaging member. Bao teaches a device for non-fusion repair of a defect in the annulus of an intervertebral disc having an expanded or enlarged end portion for retention in the defect. Michelson teaches fusion of adjacent vertebral endplates by inserting therein a device configured to penetrate and be retained in cortical bone. Due to the aforementioned differences in the

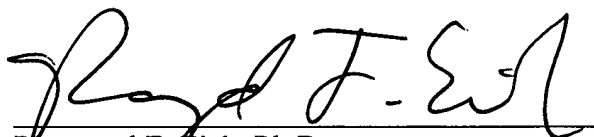
configuration of annulus- versus bone-engaging members, any attempt by the skilled artisan to incorporate the bone-engaging configuration of Michelson with the annular plug of Bao would result in an inoperable device and no reasonable expectation of success in achieving the same without undue experimentation. Therefore, Applicants request this rejection of 19-23, 25-28, 30-33, and 37 be withdrawn.

### Conclusion

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

WILLIAMS, MORGAN & AMERSON, P.C.  
CUSTOMER NO. 45488



Raymund F. Eich, Ph.D.

Reg. No. 42,508  
10333 Richmond, Suite 1100  
Houston, Texas 77042  
(713) 934-4065  
(713) 934-7011 (fax)

AGENT FOR APPLICANTS

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